

Notice of Allowability	Application No.	Applicant(s)	
	09/763,362	TOMIZUKA ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/19/07.
2. ☒ The allowed claim(s) is/are 93,104,106-108,111,112,117-124,126,135 and 138.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
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| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>See Continuation Sheet</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>9/6/07</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 11/6,12/5,6/11,4/29.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Vid Mohan-Ram on December 6, 2007.

The application has been amended as follows:

In the claims:

1. Cancel claims 26-83 and 85.
2. Delete the last two lines of claim 93 and replace with the following:
 - wherein the at least one recognition sequence of (iii) for the site-directed recombination enzyme is located between the chromosome fragments of (iv). –
3. Replace Claim 117 as follows:

A method for producing a recombinant human chromosome, comprising:

(a) preparing a first isolated cell comprising a modified SC20 chromosome fragment (Accession Number FERM BP-7583), wherein the fragment comprises the human chromosome #14 centromere and the fragment is modified to contain a recognition sequence for a site-directed recombination enzyme;

(b) preparing a second, isolated cell comprising a human chromosome fragment, which comprises (i) a human antibody gene and (ii) a recognition sequence for a site-directed recombination enzyme at a desired site in said chromosome fragment;

(c) fusing said first cell with said second cell to produce a hybrid cell; and

(d) expressing a site-directed recombination in said hybrid cell,

wherein expression of said enzyme causes site-directed recombination between the modified SC20 chromosome fragment comprising the human chromosome #14 centromere, and a portion of the second chromosome fragment, thereby producing a recombinant human chromosome.

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4. Replace claim 123 with the following:

123. The method of claim 117, wherein said recognition sequence in said modified SC20 chromosome fragment of (a) and the human chromosome fragment of (b) are loxP recognition sequences and said site-directed recombination enzyme is Cre recombinase.

5. Replace claim 124 with the following:

124. The method of claim 117, wherein said recognition sequence in said modified SC20 chromosome fragment of (a) and the human chromosome fragment of (b) are FRP recognition sequences and said site-directed recombination enzyme is FLP recombinase.

6. Replace claim 126 with the following:

126. The method of claim 117, said human chromosome fragment in (b) is a fragment of either human chromosome #2, or human chromosome #22, which comprises a human antibody light chain gene.

6. Cancel claim 136.

In the Abstract:

1. In the abstract, filed 2/21/01, (pages 360-361), delete the entire second paragraph, starting with the phrase, "The invention also relates to a method for producing a chimeric non human animal or a non-human animal."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaia N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Thursday from 7:00 to 5:00 (Eastern Standard Time). Should the Examiner be unavailable, inquiries should be directed to Peter Paras, SPE of Art Unit 1632, at (571) 272-4517. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Thaia N. Ton/
Primary Examiner
Art Unit 1632